



November 20, 2014

VIA ECFS
VIA E-MAIL

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, S.W.
Room TW-A325
Washington, D.C. 20554

Re: Notice of Ex Parte Presentation, ET Docket Nos. 13-84 and 03-137

Dear Ms. Dortch:

Pursuant to Section 1.1206 of the Federal Communications Commission's ("FCC") rules, 47 C.F.R. § 1.1206, the Association for the Advancement of Instrumentation. ("AAMI"), on behalf of its Cardiac Rhythm Management Device ("CRMD") Committee, hereby submits this letter summarizing an *ex parte* presentation in the above-referenced docket.

On November 18, 2014, Charles S. Farlow of Medtronic, Bob Stevenson of Greatbatch Medical, Paul Stadnik of Biotronik, Ron Reitan of Boston Scientific, Tushar Dharampal of St. Jude Medical, Mary Logan of AAMI and Wil Vargas of AAMI, met with Ira Keltz, Deputy Chief, Office of Engineering and Technology ("OET"), Bruce A. Romano, Associate Chief, OET, Geraldine Matise, Associate Chief, OET, Edwin Mantiply, Mathew Hussey, and Julius Knapp, Chief, OET. The attached slides were reviewed during the meeting.

Ron Reitan, Co-Chair of AAMI CRMD/Working Group 02 (EMC Test Protocols Working Group), delivered the presentation on behalf of AAMI.

Ron Reitan briefly discussed the mission and patient safety focus of AAMI before moving into the main portion of the presentation. The parties discussed two critical areas of concern highlighted in comments filed by AAMI CRMD/Working Group 02 (EMC Test Protocols Working Group) (filed comments dated Sept. 3, 2013): exposure limits (paragraph 207-209 of the NOI) and frequency range (paragraph 229 of the NOI). The presentation focused on how these areas of concern relate to Cardiac Implantable Electronic Devices ("CIED") patient safety. A 3-minute video narrated by Dr. Roger Carrillo further described the basic function of a CIED and why these devices are so critical to the lives of patients who depend on them. A transcript of Dr. Carrillo's video is also provided with this submission.

Ron explained that CIEDs currently conform to ISO 14117:2012. This FDA-recognized standard establishes immunity requirements for cardiac devices when patients are exposed to electromagnetic fields from 0 Hz to 3 GHz. Slides 13-18 illustrate the differences between ISO 14117:2012 test levels and Maximum Permissible Exposure ("MPE") levels specified by ICNIRP

1998, ICNIRP 2010, and several IEEE C95 standards. Slides 19 and 20 explain the design trade-offs and longevity considerations related to adopting MPE limits that exceed those specified by ICNIRP 1998. In his discussion of slide 21, Ron reviewed several requirements of the National Environmental Policy Act of 1969 (“NEPA”) and proposed that CIED patients are part of the “human environment”. Ron briefly reviewed WG02 responses to comments filed by Sensormatic, Inc. and concluded the presentation by reviewing two recommendations and one summary slide.

The parties discussed the implications of AAMI’s recommendations, especially those related to FCC consideration of patients implanted with CIEDs in the rulemaking proceeding and how such an action may set a new precedent. The parties then discussed past and future engagement with the Electronic Article Surveillance industry as well as implications related to new technologies such as electric vehicle charging systems.

In the presentation, WG02 suggested a staged adoption of new limits by the Commission. Representatives from the FCC indicated the Commission would certainly consider these inputs but was not going to reach a decision in the near future. In response to a question about interference incidents, Ron invited the Commission to attend the AAMI CRMD meeting scheduled for Nov. 20, 2014 where this topic will be discussed. The Commission declined this invitation but said they have frequent contact with the Food & Drug Administration about this topic and related matters.

Mr. Knapp declined WG02’s request for liaison but added the Commission is willing to meet with the group under *ex parte* rules in the future.

Pursuant to Section 1.1206, a copy of this letter is being filed via ECFS for inclusion in the above-referenced docket. Please contact the undersigned with any questions.

Respectfully,

/s/Wil Vargas

Wil Vargas

Director, Standards

AAMI

/s/Bob Stevenson

Bob Stevenson

Co-Chair

AAMI Cardiac Rhythm

Management Device Committee

/s/Dr. Roger Carillo

Dr. Roger Carrillo

Co-Chair

AAMI Cardiac Rhythm

Management Device Committee

Attachments

cc (via email): Edwin Mantiply
Mathew Hussey
Bruce Romano
Julian Knapp
Ira Keltz
Geraldine Matise

Briefing for the Federal Communications Commission

Radio Frequency Exposure Considerations for Cardiovascular Implantable Electronic Devices (CIEDs)

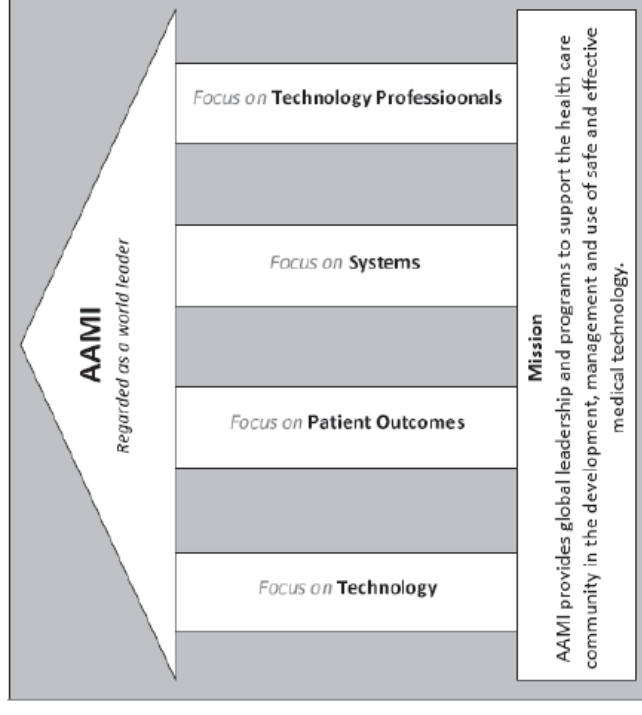
Ronald C. Reitan
Boston Scientific, Inc.
Co-Chair AAMI CRMD/WG02

Nov. 18, 2014

Agenda

- Introduction & purpose
- CIED therapies
- Physician's statement
- CIED sensing and EMC standards
- NEPA
- Other filings
- Recommendations
- Summary

- **Mission:** Support the healthcare community in development, management and use of safe and effective medical technology.
- **AAMI's Best Role:** Convening diverse groups to solve problems (e.g., standards development, summits, patient safety workgroups, white papers, safety-oriented research, guidance documents)
- **Professional society:** Not a “trade association”



Who is AAMI?

- Engineering, medicine, nursing, industry and government professionals
- 7,000 members – individual members or representatives of:
 - Hospitals, industry and government
 - R&D, QA/RA professionals, engineers
 - Doctors, nurses, technicians, students
 - Academic and government researchers
 - Consultant experts
- Over 300 corporate and institutional members
 - FDA is “sustaining” member



Introduction

- The AAMI Cardiac Rhythm Management Device (CRMD) Committee is responsible for development of a number of performance standards for Cardiovascular Implantable Electronic Devices (CIEDs) used to treat cardiac arrhythmias and heart failure
- The AAMI CRMD Committee also serves as the US Technical Advisory Group (TAG) to International Standards Organization (ISO) TC 150/SC 6/JWG 1 (Cardiac pacemakers and defibrillators)

Introduction

- Members of AAMI CRMD and associated working groups include physicians, implantable cardiac device manufacturers, and the FDA
- Participants in today's meeting represent manufacturers that produce over 95% of CIEDs sold in the United States



Why we are here

- AAMI CRMD/WG02 (EMC Test Protocols Working Group) filed comments in ET Docket No. 13-84 and ET Docket No. 03-137 on Sept. 3, 2013
- The highest priority of the AAMI CRMD committee is the safety of CIED patients
- The purpose of this ex parte meeting is to further explain how the areas of concern raised in our filed comments relate to CIED patient safety
 - I. EXPOSURE LIMITS (Regarding paragraph 207-209 of the NOI)
 - II. FREQUENCY RANGE (paragraph 229 of the NOI)

CIED therapies

Disease states	Device types
Risk for Sudden Cardiac Arrest	ICD
Bradycardia (slow heart rate, AV Block)	Pacemaker (single, dual)
Tachycardia (high heart rate)	ICD
Heart Failure	CRT-P, CRT-D

SCA (Sudden Cardiac Arrest) accounts for more than 350,000 deaths in the U.S. each year and is one of the leading causes of death in the United States each year. In fact, SCA (Sudden Cardiac Arrest) claims one life every 90 seconds, taking more lives each year than breast cancer, lung cancer or AIDS.¹

¹Last accessed Oct. 15, 2014, <http://www.hrsonline.org/Patient-Resources/Heart-Diseases-Disorders/Sudden-Cardiac-Arrest-SCA#axzz3GFcfoU6>

Implant Population Statistics (2009)

- Pacemakers: In 2009, 1M worldwide, 738,000/yr new implants (236,000 in USA)². Estimated pacemaker total ~3M in 2014³
- ICDs: In 2009, 328,000 worldwide, 222,000/yr new implants (133,262 in USA)².

²The 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009—A World Society of Arrhythmia's Project, Pacing and Clinical Electrophysiology, V34, Issue 8, pp1013-1027, August 2011

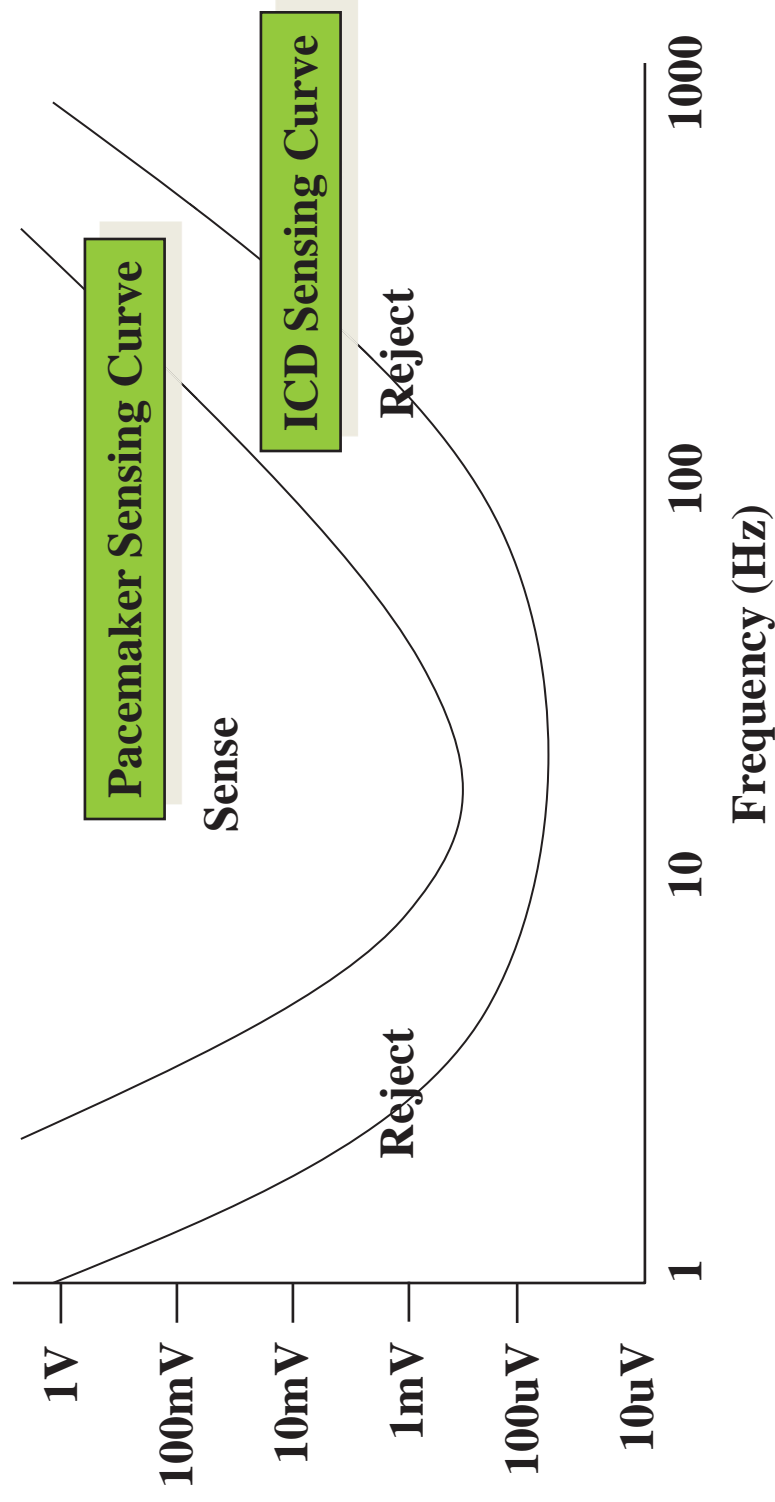
³Cardiac Pacemakers from the Patient's Perspective, Circulation:2002;105:2136-2138

Physician's Statement

- Roger Carrillo, MD, FHRS
- Chief of Surgical Electrophysiology University of Miami, FL
- 25 years of experience with implantable cardiac devices
- Medical Co-Chair of AAMI Cardiac Rhythm Management Committee



CIED Sensing

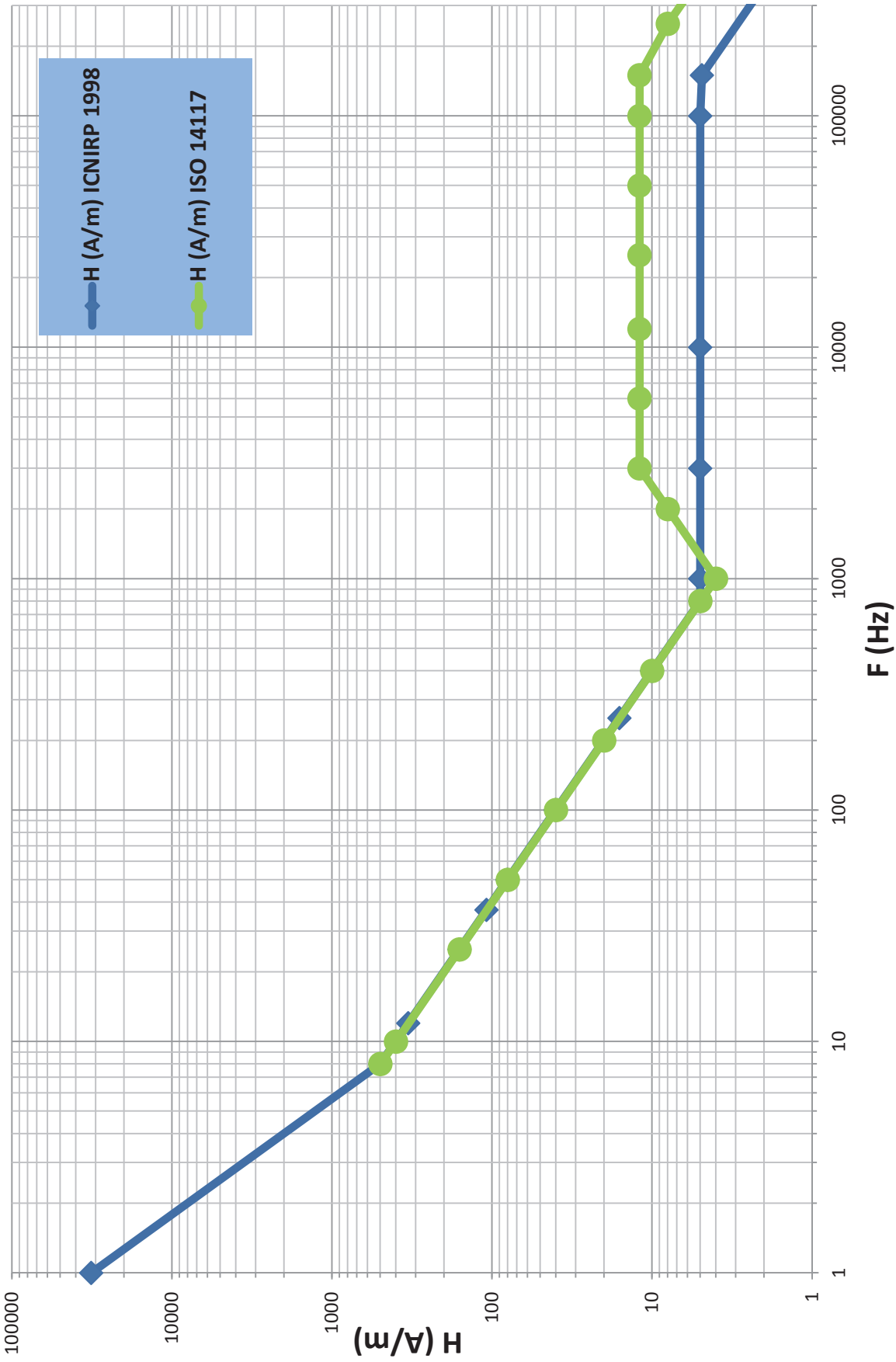


CIED EMC Standards

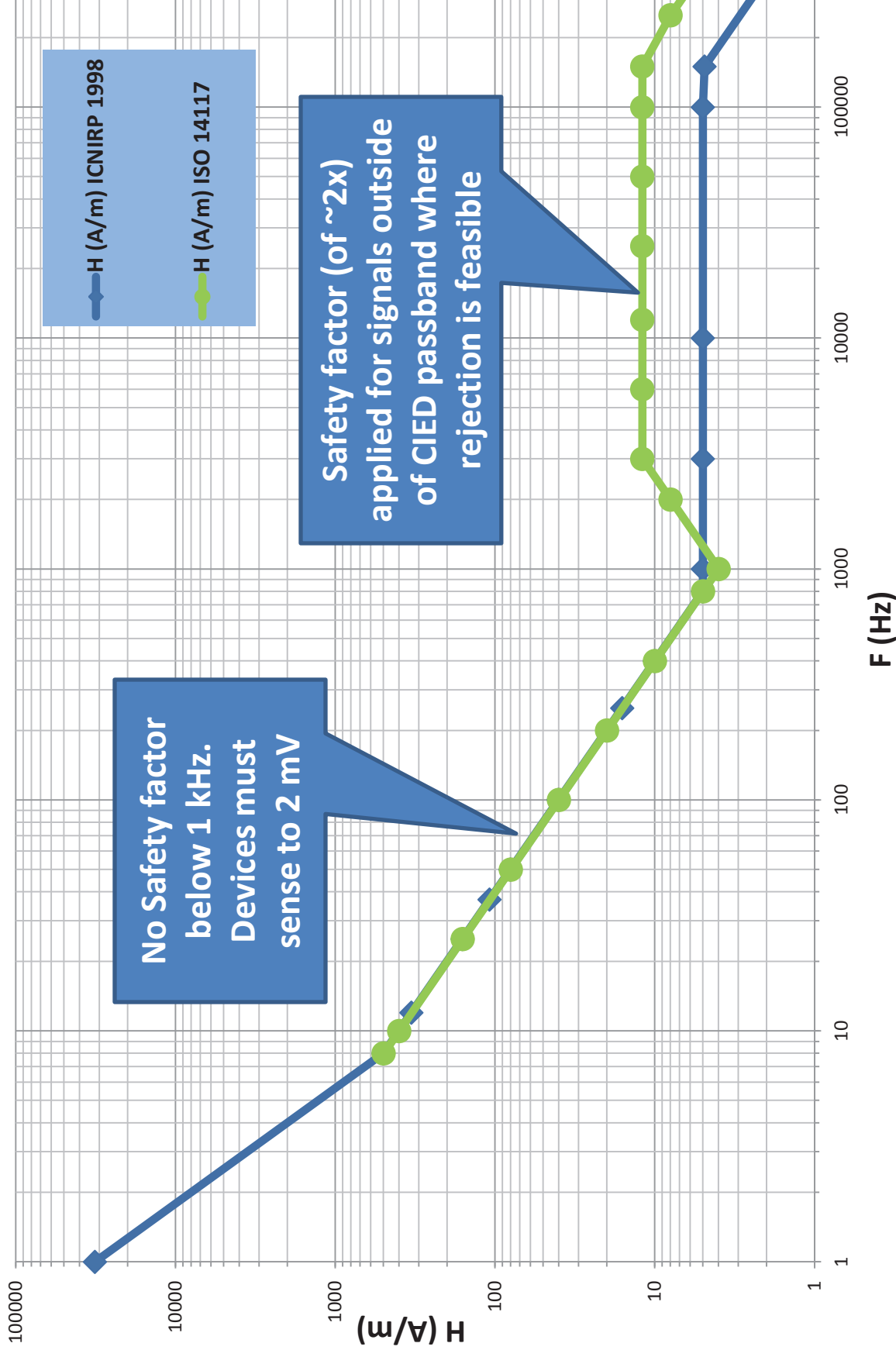
- The FDA-recognized CIED EMC standard, ISO 14117:2012⁴, establishes immunity requirements for cardiac devices when patients are exposed to electromagnetic fields from 0 Hz to 3 GHz
- To establish immunity levels (below 300 kHz), the authors of ISO 14117 and its predecessors (e.g., AAMI PC69:2000) multiplied general public MPE levels from ICNIRP 1998 by a safety factor to determine the test level at which interference might be expected at the sensing ports of cardiac devices (illustrative figures follow this page)

⁴ISO 14117:2012 *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices*

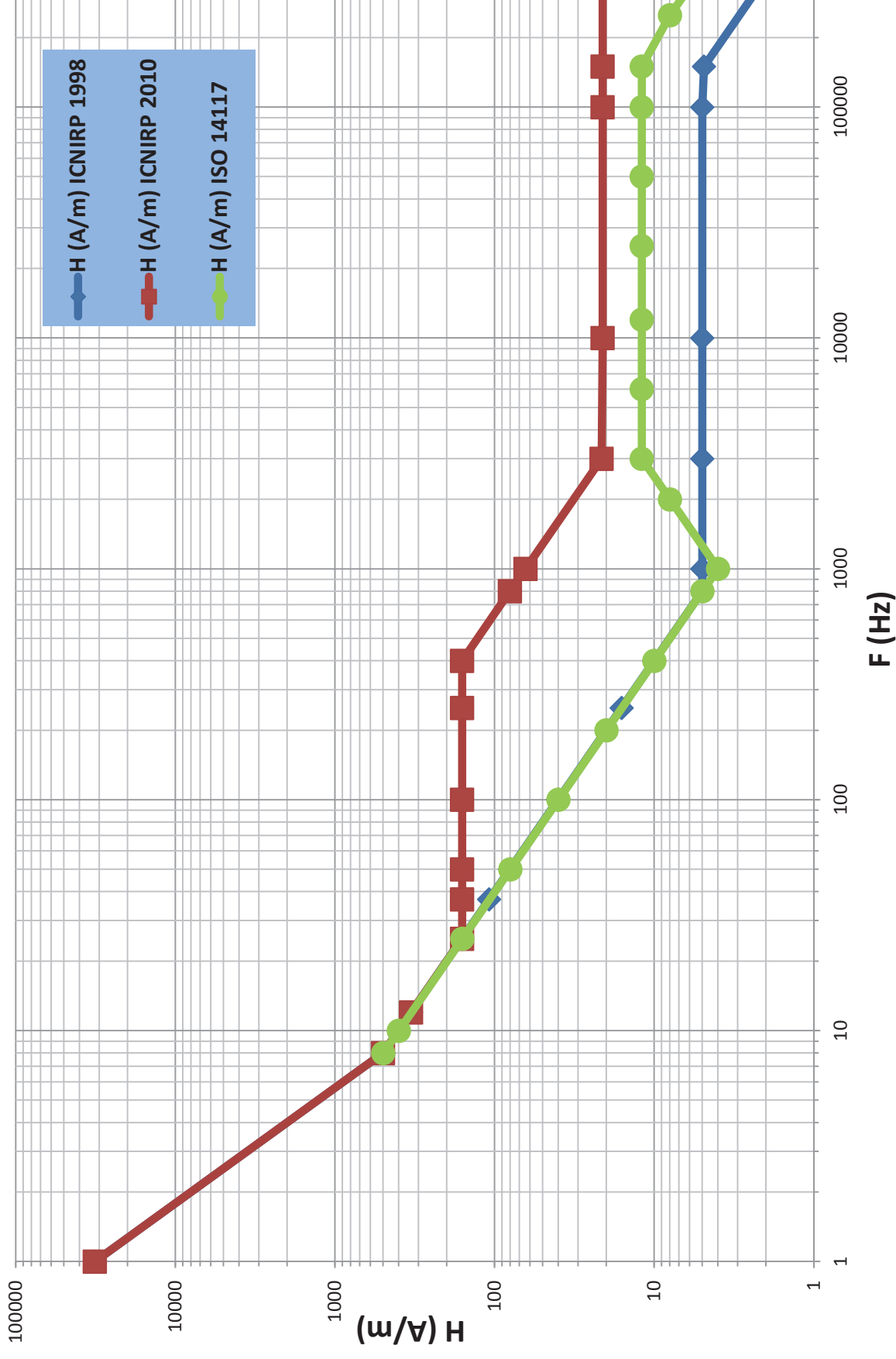
ISO 14117 Low Frequency Magnetic Field Immunity vs ICNIRP 1998 GPRL



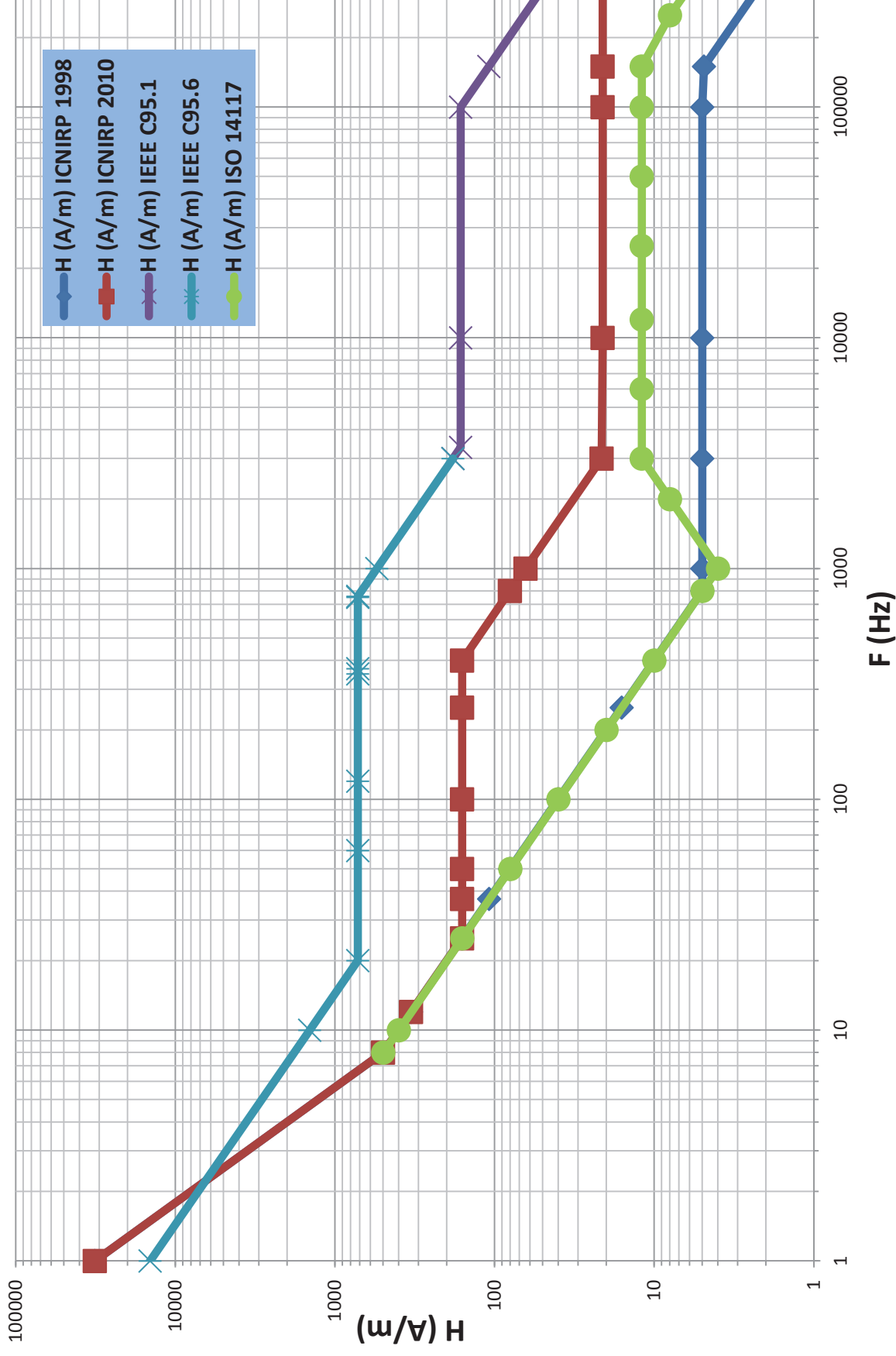
ISO 14117 Low Frequency Magnetic Field Immunity vs ICNIRP 1998 GPRL



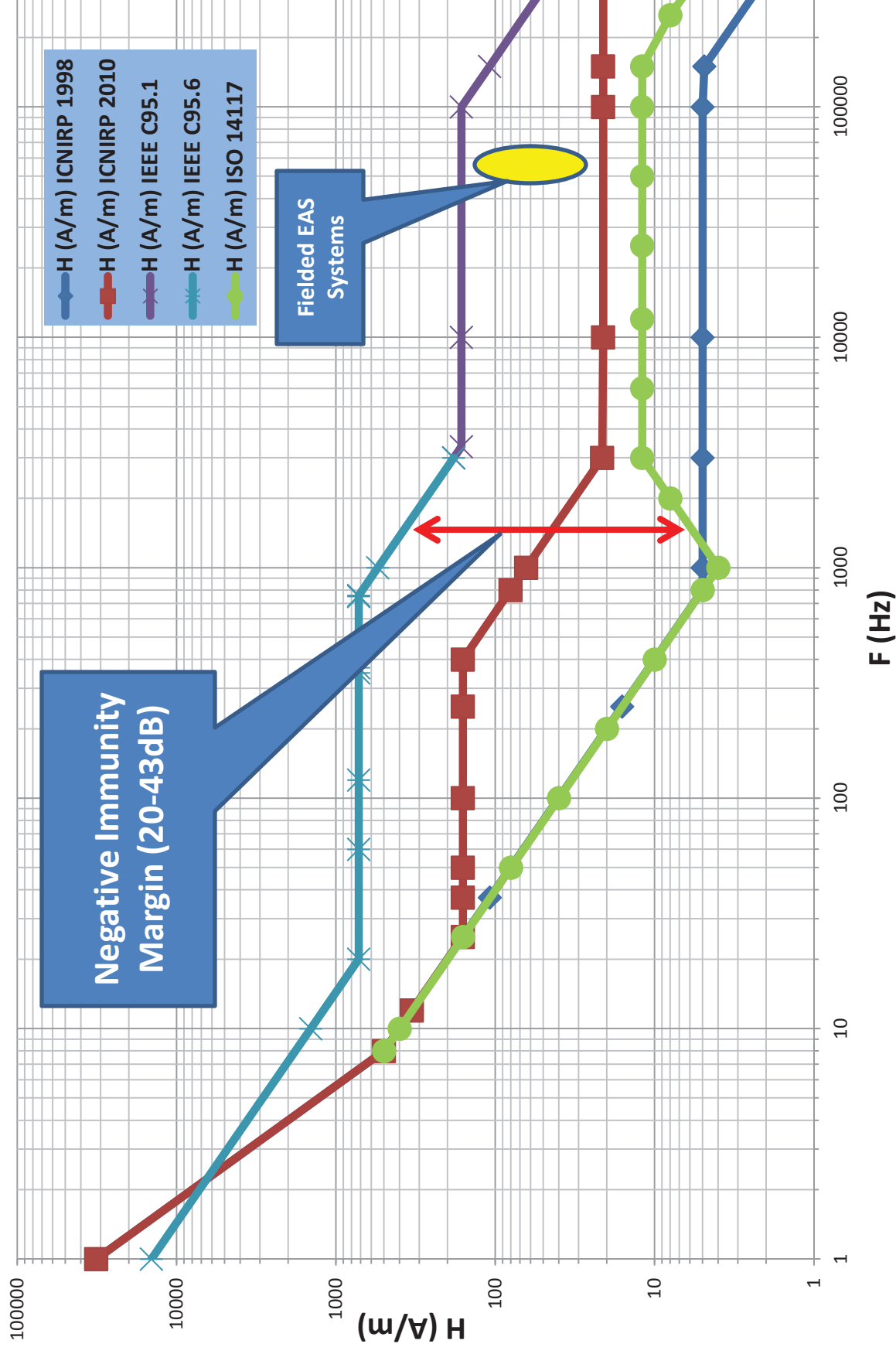
Consequence of adopting ICNIRP 2010 GPRL as MPE



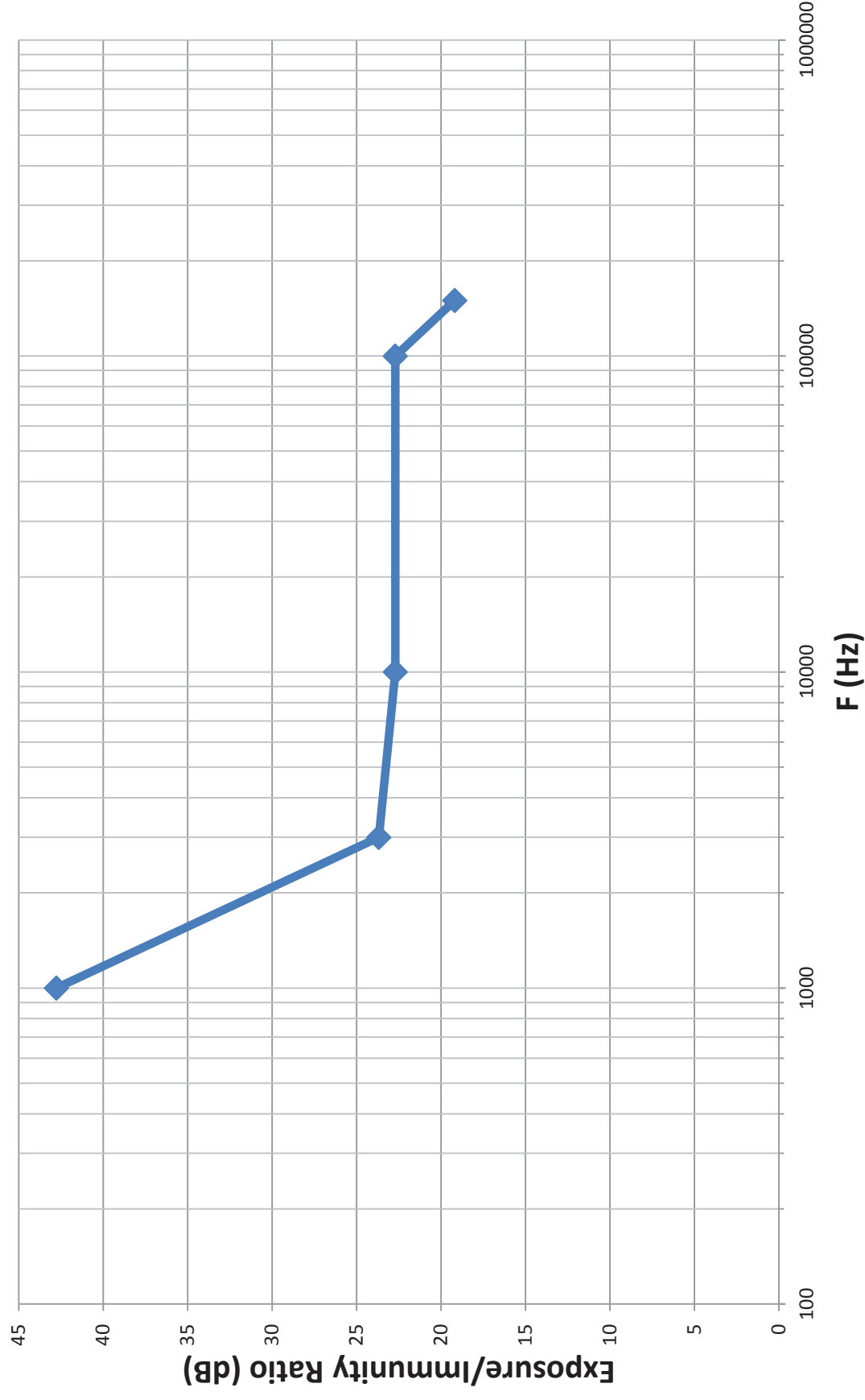
Consequence of adopting IEEE C95.x as MPE



Consequence of adopting IEEE C95.x as MPE



MPE (IEEE C95) to ISO Immunity Ratio



CIED Device Immunity Gap with IEEE C95.x MPE Limits

- With a similar safety factor, for frequencies above 1 kHz, CIED stop-band rejection would have to be increased by ~40 dB
- To do so will require increases in digital filter order and design approach that are unlikely to close the gap
 - Additional power consumption → reduced device longevity → increased patient risk for device changeout
 - Design and approval cycle for new IC's and device designs of many years
- The induced voltage seen at the device above 100 kHz will likely exceed the feasible dynamic range → degraded device performance → increased patient risk

Patient Safety Risk related to increased MPE levels is not readily mitigated

- CIED's have a service life ranging from 6 to as much as 15 years
- From the time of introduction of MPE limits that exceed ICNIRP 1998 GPRs, approximately 20 years will pass before devices with improved immunity will entirely replace devices tested to the current standard
- During this time, millions of CIED patients may be subject to increased risk of inappropriate or absent therapy due to low frequency EMI from newly approved technologies operating at the increased MPE limits
- Independent research arrived at similar conclusion:

*"Since interference is encountered already at yet existing systems, the situation would be worse if future systems would further increase their emissions by making use of the elevated reference levels recommended in updated exposure guidelines."*⁵

⁵Impact of EAS Systems on Implanted Cardiac Pacemakers and Defibrillators, Journal of Electromagnetic Analysis and Applications, 2013, 5,67-73

NEPA

- The FCC is required by the National Environmental Policy Act of 1969, among other things, to evaluate the effect of emissions from FCC-regulated transmitters on the quality of the human environment^{6,7}
- Specific procedures are codified in 47 C.F.R. §1.1301 through §1.1319
- CIED patients ARE a part of the human environment

⁶<http://www.fcc.gov/encyclopedia/radio-frequency-safety>

⁷<http://transition.fcc.gov/oet/rfsafety/background.html>

Other filings

- Response to Comments from Sensormatic, Inc.
 - The trend in EAS system deployment is to make them concealed
 - Members of AAMI CRMD do not believe that current FDA Guidance⁸ is being followed during the deployment of EAS systems
 - We are not asking the FCC to “expand this proceeding to address EMC” as claimed by Sensormatic; rather, we are asking the Commission to consider FDA-recognized CIED EMC standards and fundamental device limitations during the development of MPE levels below 300 kHz
 - Yes, the FDA regulates “medical implant safety” but the FCC plays a role in regulating the human environment where the patient resides

⁸FDA Guidance for Industry, *Labeling for Electronic Anti-Theft Systems*, August 15, 2000

Recommendations

1. In their consideration of the “human environment”, the FCC should include those humans who are implanted with CIEDs
 - These devices sense cardiac rhythms from biological tissue and provide therapies to biological tissue
 - CIED patients expect to freely move throughout the public environment without fear of therapy degradation or cessation; as do humans without an implanted device

Recommendations

2. The FCC should consider adoption of ICNIRP or IEEE MPE limits in a staged manner that allows time for the CIED manufacturers, patients and their physicians to safely manage the risks of doing so:
 - Immediately adopt ICNIRP 1998 GPRL below 300 kHz with an exception for existing equipment
 - Members of AAMI CRMD/WG02 will perform investigational testing and analysis with the goal of increasing CIED immunity levels in future versions of ISO 14117
 - After a period of 5 years, open a new rulemaking that would consider the status of ISO 14117 and other factors

Summary

- Members of AAMI CRMD welcome the establishment of a formal liaison with the FCC to lend our expertise as the Commission develops additional rules in this area
- Our priorities are patient safety and the effectiveness of therapeutic and diagnostic CIEDs
- We do not want prospective patients to be discouraged from receiving life-saving CIED therapies because of concerns about the public electromagnetic environment
 - When asked “Are you aware of, or do you believe that there are instances of patients who choose not to receive a device out of fear of losing their current job or profession due to EMI in the workplace?”, 50% of the over 300 physicians present responded “Yes”⁹

⁹*Patient Discrimination in the workplace: Result of a new European Initiative*, Proceeding of the HRS JS06, May, 2012

Transcript of narrative provided by Dr. Roger Carrillo

Slide 1:

My name is Dr. Roger Carrillo. I am the medical co-chair of the AAMI Cardiac Rhythm Device Management Committee.

Slide 2 (animated beating heart receiving bradycardia therapy):

Pacemakers are tiny devices that are implanted under the skin. They are connected to the heart with leads or wires. When the heart beats slowly, the device stimulates the heart restoring normal rhythm.

Slide 3:

In this X-ray, you can appreciate the device and the leads, both in the anterior and lateral projections.

Slide 4:

An implantable cardiac defibrillator is connected to the heart with leads. When the patient goes into a fast and lethal rhythm, the device shocks the patient back into normal rhythm.

Slide 5:

In this X-ray, you can see the implantable cardiac defibrillator and the leads both in the anterior and lateral projection.

Slide 6 (short movie):

In this video, you can see a young, 26-year old soccer player that collapses on the floor from a lethal rhythm. His implantable cardiac defibrillator shocks him back into normal rhythm restoring his life. Like him, many patients with implantable cardiac defibrillators, have their lives saved within seconds, many times.

Screen-captures of essential scenes in the narrated short movie of slide 6











Slide 7:

There are more patients with electrical implantable cardiac devices in the United States, than working nurses. And patients of all ages, from newborns to seniors, have implantable cardiac devices.

Slide 8:

Every year, over 350,000 new implants are performed in the United States.

Slide 9:

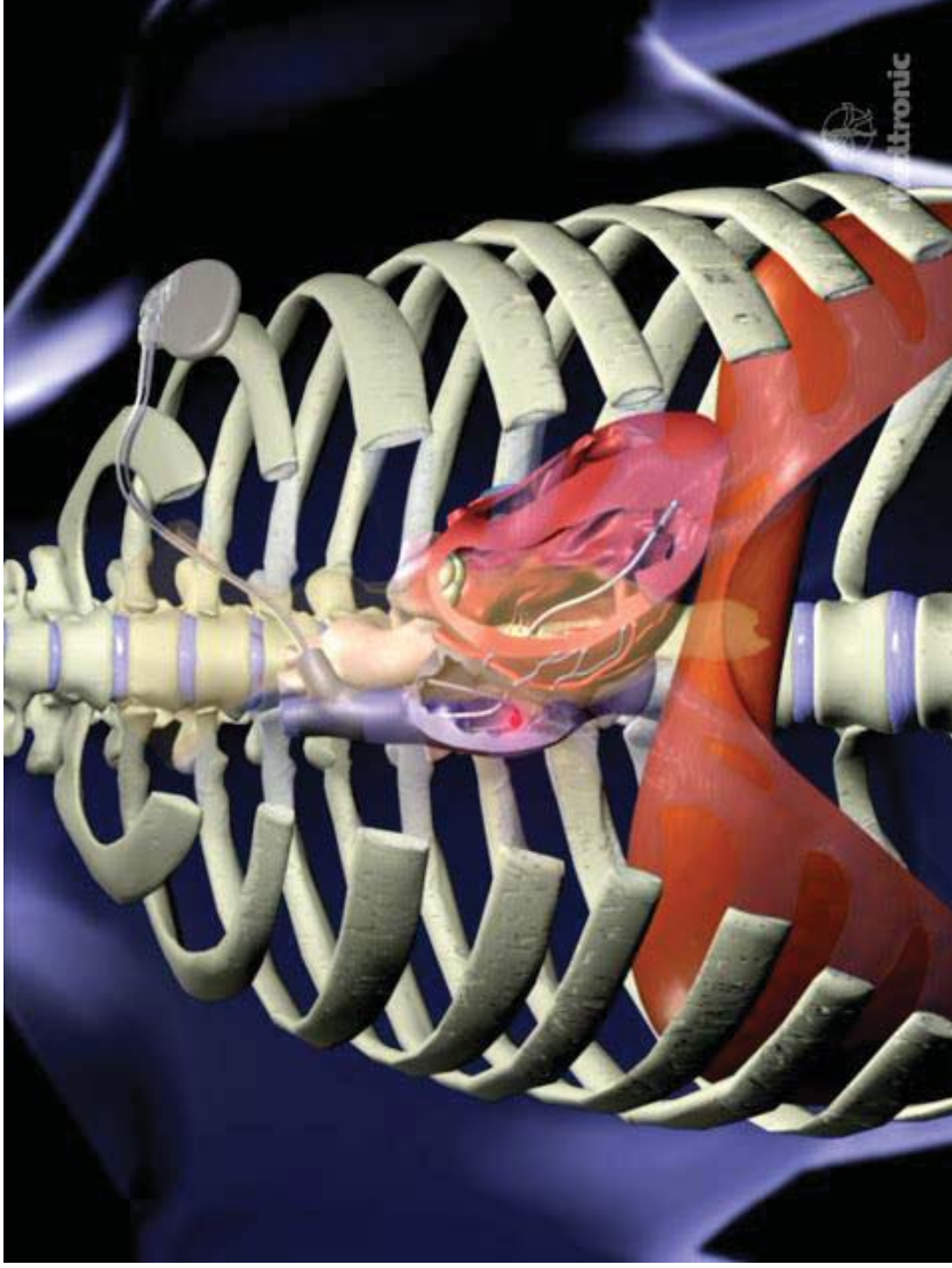
Patients with implantable cardiac devices are exposed to an electrical environment in the hospital, and work, and in their personal lives. This includes home and daily activities. They have fear. They are anxious, that these environmental electrical devices may interfere with the function of their own device. I greatly appreciate any help that you can offer to mitigate their fears. Thank you.

Physician's Statement

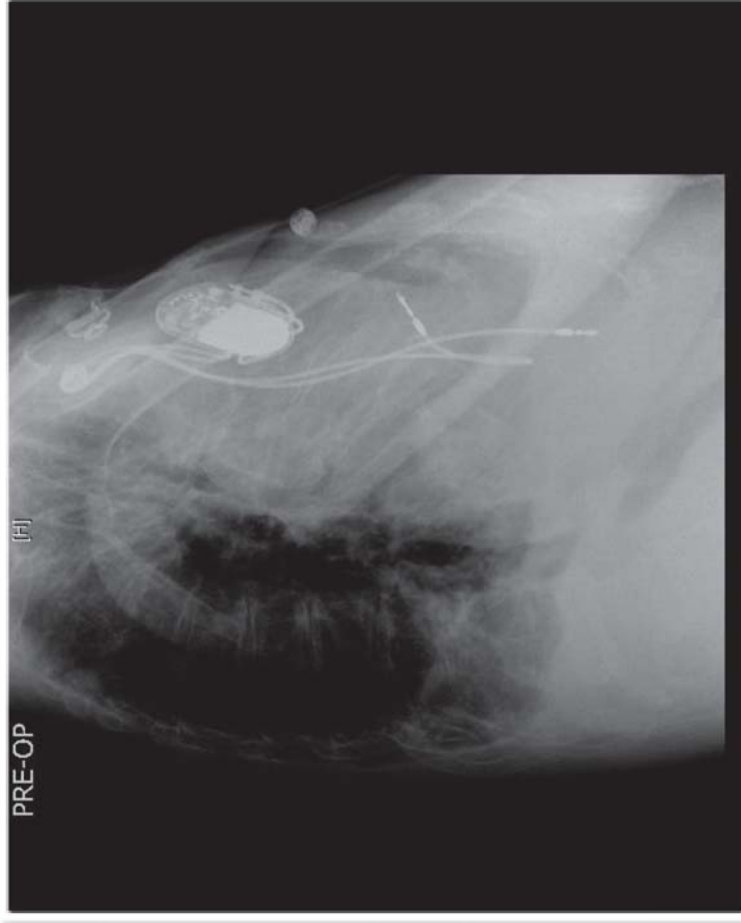
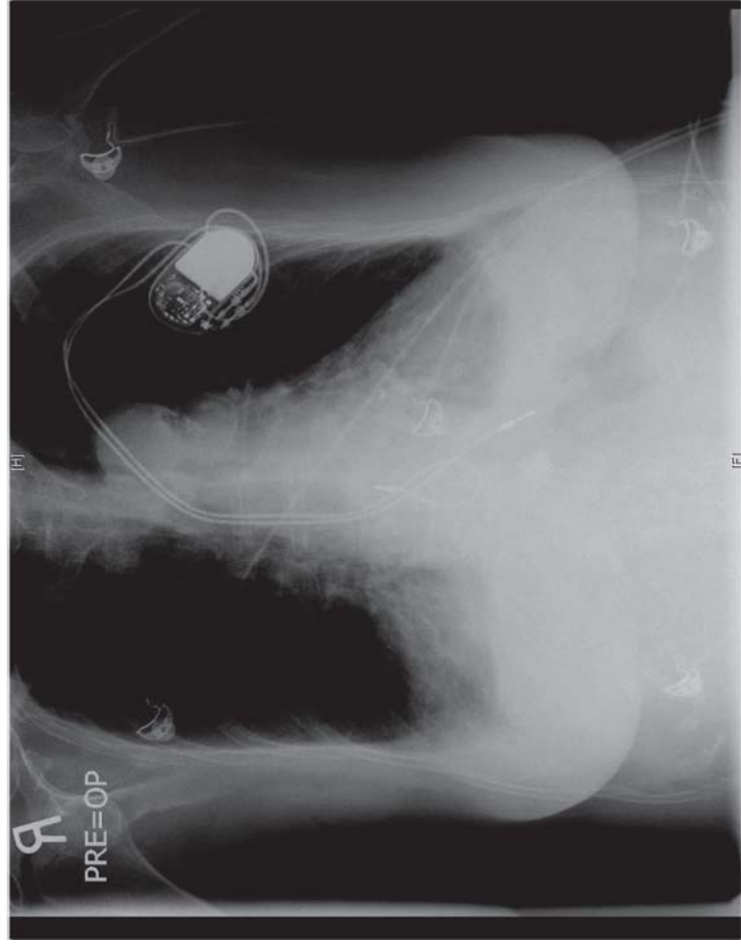
- Roger Carrillo, MD
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Pacemaker Function



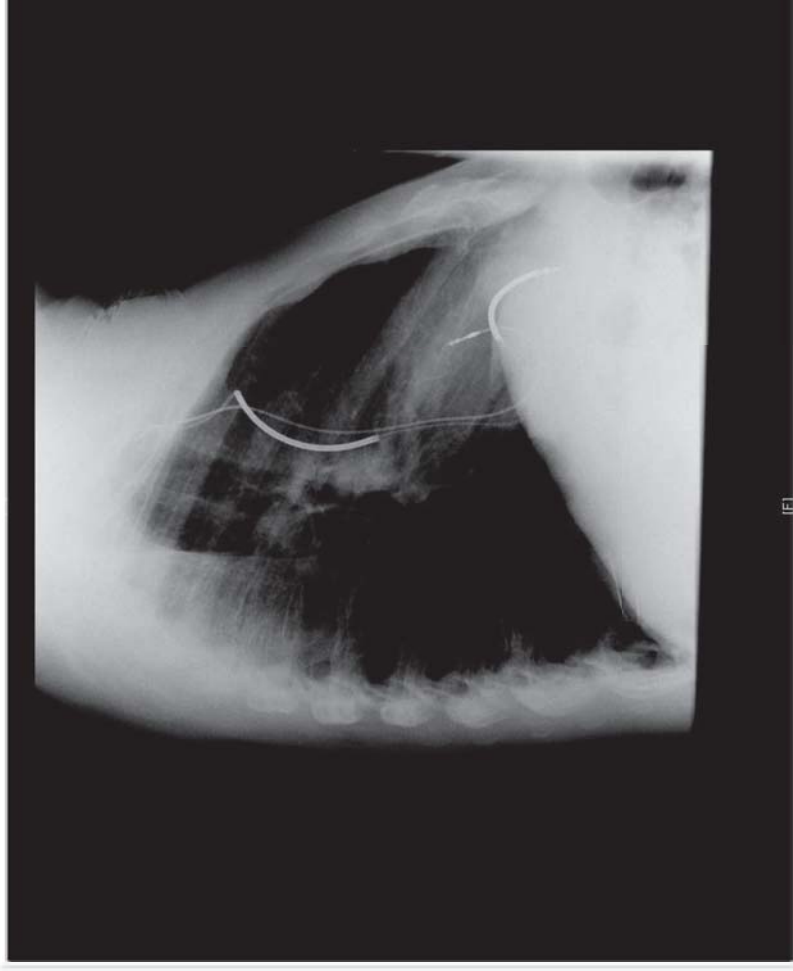
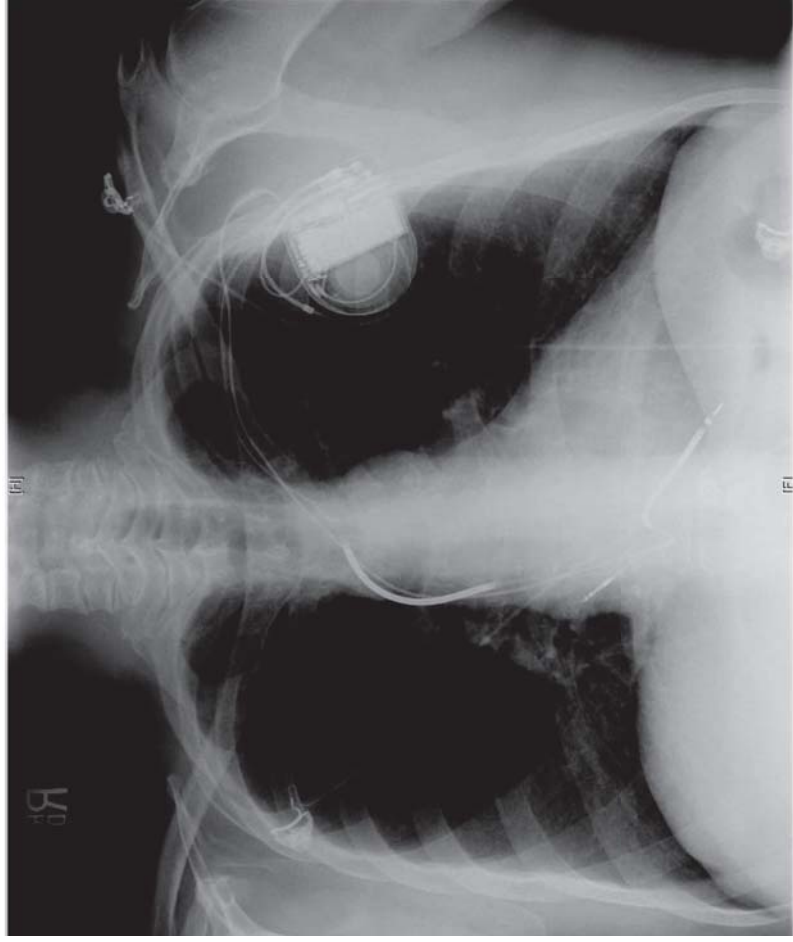
Fluoroscopy of pacemaker/leads



VF and ICD

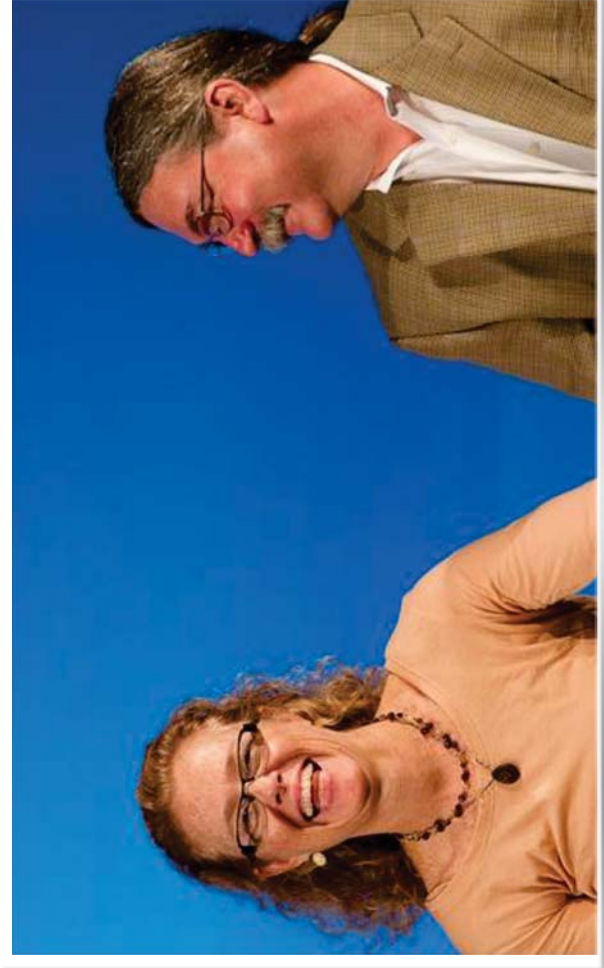


Fluoroscopy of ICD/leads

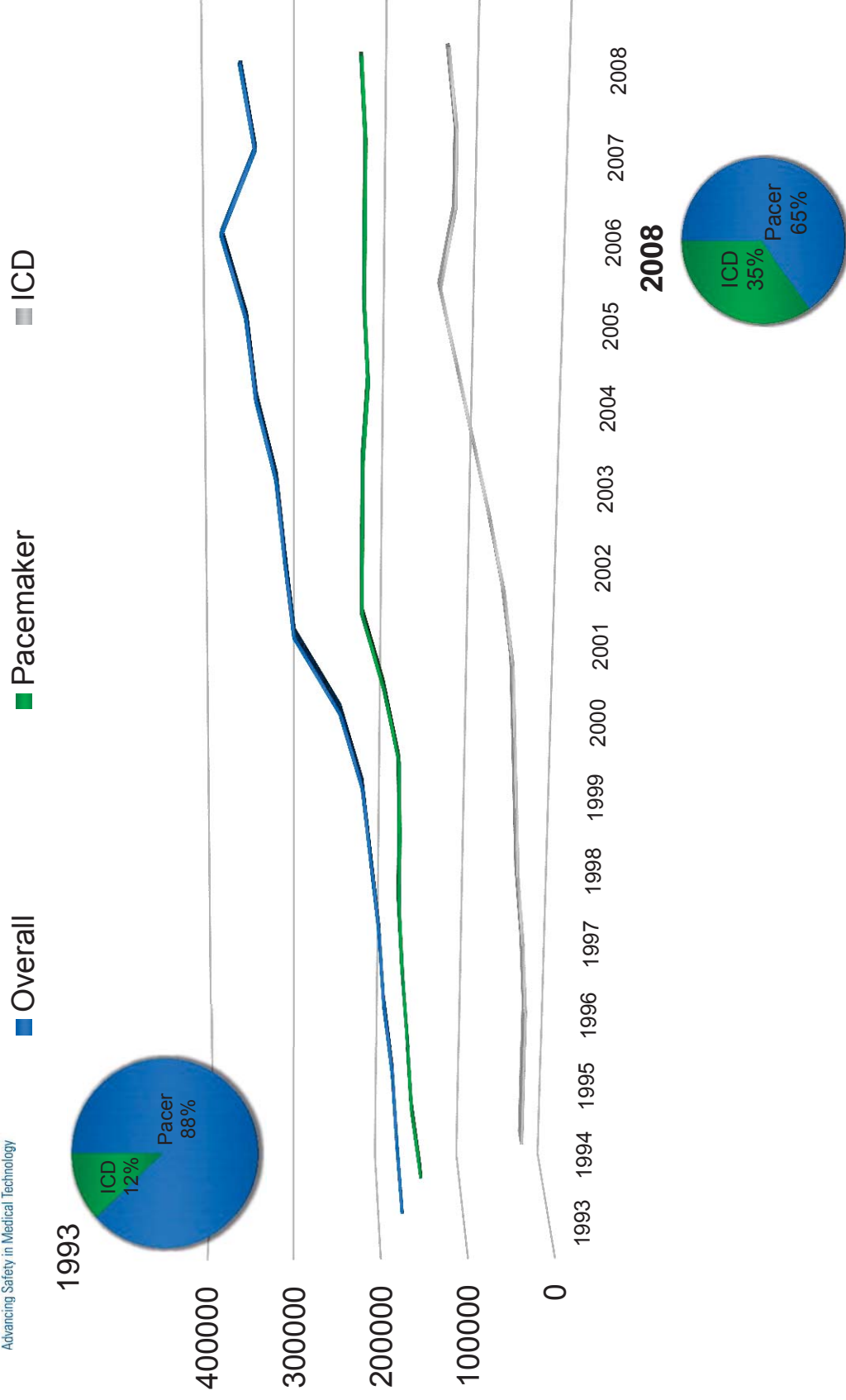




- There are more **patients** with electrical implantable cardiac devices than working **nurses** in the United States
- Patients of all ages, from newborns to **seniors**



1993-2008 USA implantation data



Greenspoon A, Patel J, Lau E, Ochoa J, Frisch D, Ho R, Pavri B and Kurtz S. Sixteen-year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States. J Am Coll Cardiol 2011;58:1001-6

Electrical Environment

